K003576

JAN 2 5 2001

QUINTON
your heart company

510(k) Summary

1. Name: Quinton Instrument Company
2. Address: 3303 Monte Villa Parkway
   Bothell, WA 98021-8906
3. Phone number: (425) 402-2484
4. Fax number: (425) 402-2017
5. Contact person: David Himes
6. Summary prepared: 11/17/00
7. Proprietary name: Q-Tel RMS (rehabilitation management system)
8. Common name: Telemetry system
9. Classification name:
   § 870.1025 Arrhythmia detector and alarm
   § 870.1425 Programmable diagnostic computer
   § 870.2050 Biopotential amplifier and signal conditioner
   § 870.2300 Cardiac monitor
   § 870.2340 Electrocardiograph
   § 870.2810 Paper chart recorder
   § 870.2900 Patient transducer and electrode cable
   § 870.2910 Radiofrequency physiological signal transmitter and receiver
10. The Q-Tel RMS is substantially equivalent to the Q-Tel Telemetry System v. 6.0 (ST) (K992908).
11. Description: The Q-Tel RMS telemetry system measures the electrical activity of a patient's heart during an exercise class and transmits it via radio frequency to a central monitoring station. The core features of the Q-Tel RMS system include telemetry monitoring, ECG displays, full disclosure of vital signs, printing and reporting, and rehabilitation program management, such as scheduling classes and seminars and patient enrollment.
    The monitoring station displays the patient's real-time ECG waveforms and uses programmable alarms to indicate the presence of pre-selected medical or technical conditions, such as arrhythmia or loss of signal. When alerted by the alarm, the clinician determines whether the event causing the alarm is clinically significant or benign. The Q-Tel RMS system enables the clinician to view, edit, record ECG strips, and use a printer to print reports.

Phone |425| 402.2000 Toll Free |800| 426.0337
3303 Monte Villa Parkway, Bothell, WA 98021-8906

QUINTON
your heart company

12. Intended use:

- The device is intended to acquire and transmit electrocardiograph (ECG) data by means of a radio-frequency transmitter worn by individual patients in a hospital or clinical setting to a central monitor where it is received, displayed, stored, and analyzed, with alarms for heart rate, arrhythmia, and ST change.
- ECG analysis may include 12-lead ECG interpretation.
- The device is to be used on ambulatory adult populations where monitoring is prescribed while undergoing exercise rehabilitation.
- Multiple central receivers may be used and connected to a local area network.
- Patient demographics, exercise prescription, scheduling information, and collected data can be ported to an outcomes management program.

13. Technological characteristic comparison: The Q-Tel Telemetry System v. 6.0 (ST) (K992908) and the proposed device have nearly identical indications for use. 12-lead capabilities will be optional on the proposed device to provide additional data. The proposed device allows the clinician to schedule seminars or classes and provide reports on those items. This is merely a management tool and has no impact on the safety and efficacy of the device. Both devices are to be to be used on ambulatory adult populations where monitoring is prescribed while undergoing exercise rehabilitation. Both devices are based on personal computer (PC) platforms. The predicate device utilized a Pentium II processor while the proposed device utilizes a Pentium III processor, a proven performance improvement. The Windows 2000 operating system coupled with SQL 2000 (MDSE) is used in lieu of MS-DOS on the predicate device. Again, this is a proven performance improvement in addition to providing a friendlier user environment. The receiver frequency band has been shifted from 174 to 216 MHz to 904.7 to 925.16 MHz. This modification reduces the risk of electromagnetic interference (EMI), as the Federal Communications Commission (FCC) is reallocating unused television channels in the range of channels 7-13 (174 to 216 MHz) to allow television stations to test and transmit digital television (DTV) signals. The Mortara Instrument, Inc. Ambulatory X-12 Telemetry Module (K974149) has been incorporated as a component in the proposed device to accomplish the aforementioned frequency shift. The proposed device utilizes proven Mortara analysis algorithms previously incorporated in the Datex-Ohmeda CS/3 Telemetry System (K000882). Material differences between the two devices are consistent with design. Both devices perform identically, aside from the capability of the proposed device to schedule and manage classes and seminars. This represents a clinical process improvement and has no impact on the safety and/or efficacy of the device. Sterilization is not required for either device. Both devices utilize a biocompatible medical grade Santoprene that come into contact with the patient (patient leads). Mechanical safety, aside from stability, is not applicable for either device. Stability testing of the predicate and proposed devices was performed in accordance with UL 544 Safety for medical and dental equipment and IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety, respectively. Chemical safety is not applicable for either device. Both devices are used in identical anatomical sites. The proposed device adds optional 5 and 12 lead combinations, providing the clinician with more analytical data. This enhances efficacy in some instances and has no impact upon safety. Human factors for both

Phone |425| 402.2000 Toll Free |800| 426.0337
3303 Monte Villa Parkway, Bothell, WA 98021-8906

devices are similar. Generated data is identical. However, the proposed device allows the user to configure data to a desired format and schedule seminars and classes. This enhancement has no affect on safety or efficacy. Both devices are passive and floating. The existing and proposed devices utilize 9V and 2 AA batteries, respectively. Both battery combinations represent safety extra low voltage (SELV) levels and are used for radio-frequency (RF) transmission only. The proposed device complies with IEC 60601-1-2 Medical Electrical Equipment – Part 1: General Requirements for Safety: Electromagnetic Compatibility – Requirements and Tests, a more thorough standard than that of the predicate device. The predicate device complied to IEC 801 Electromagnetic compatibility and CISPR 11 Industrial, scientific, and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement, now components of IEC 60601-1-2. Both devices shall be used in a clinical or hospital environment. Electrical safety testing of the predicate and proposed devices was performed in accordance with UL 544 Safety for medical and dental equipment and IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety, respectively. Additionally, the proposed device complies with EN 60601-2-25, Medical electrical equipment. Part 2: Particular requirements for the safety of electrocardiographs. IEC 601-2-25: 1993, 1995. Thermal safety of the predicate and proposed devices is assured by compliance with UL 544 Safety for medical and dental equipment and IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety, respectively. Ionizing energy is not emitted by neither device.

Phone |425| 402.2000 Toll Free |800| 426.0337
3303 Monte Villa Parkway, Bothell, WA 98021-8906

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2001

Ms. Karen Browne
Quinton Instrument Company
3303 Monte Villa Parkway
Bothell, WA 98021-8906

Re: K003576
Trade Name: Q-Tel RMS (Rehabilitation Management System)
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: November 17, 2000
Received: November 20, 2000

Dear Ms. Browne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003576

Device Name: Q-Tel RMS

Indications For Use:

- The device is intended to acquire and transmit electrocardiograph (ECG) data by means of a radio-frequency transmitter worn by individual patients in a hospital or clinical setting to a central monitor where it is received, displayed, stored, and analyzed, with alarms for heart rate, arrhythmia, and ST change.
- ECG analysis may include 12-lead ECG interpretation.
- The device is to be used on ambulatory adult populations where monitoring is prescribed while undergoing exercise rehabilitation.
- Multiple central receivers may be used and connected to a local area network.
- Patient demographics, exercise prescription, scheduling information, and collected data can be ported to an outcomes management program.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003576

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)